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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,889	06/04/2007	Peter Svete	33668US-PCT	3731

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EXAMINER	
RAO, SAVITHA M	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
11/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,889	SVETE ET AL.	
	Examiner	Art Unit	
	SAVITHA RAO	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/14/2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,18 and 19* is/are rejected.

7)☒ Claim(s) *7-10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

DETAILED ACTION

Claims 1-10 and 18-19 are pending.

Receipt and consideration of Applicants' amended claim set and remarks/arguments filed on 08/14/2009 is acknowledged. Claims 1 and 18 are amended and are under consideration in the instant office action.

Applicants' arguments, filed 08/14/2009 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

Claims 7-10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

New grounds of rejection necessitated by the newly submitted claims filed on 08/14/2009.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 and 18-19 and are rejected under 35 U.S.C. 103(a) as being unpatentable over to Antoncic et al. (US 7271269).

Antoncic et al. discloses a potassium salt of losartan characterized by a powder X-ray diffraction pattern with peaks at about 2θ 6.9, 13.8, 20.6, 24.8, 28.7, 29.2° (Form X) (column 14, lines 14-17) and pharmaceutical composition containing polymorphic forms of losartan specifically the form exhibiting strongest diffractions at around 2θ 6.9, 13.8, 20.6, 24.8, 28.7, 29.2° (Form X) (column 15, lines 41-42 and lines 63-65). Antoncic et al. discloses an aspect of their invention where in the pharmaceutical active ingredient of the composition is the amorphous form of losartan (column 17, lines 11-16) film coated tablet formulations of potassium salt of losartan with suitable excipients (column 16, lines 12-21) . The examples 50, 52a and 52b disclosed by Antoncic et al. describe the coated tablet formulations of polymorphic forms of potassium salt of losartan. Excipients claimed in the instant claim 1, 6 and 18 are explicitly taught in these

examples. The following table lists the taught excipients along with the %weight in each formulation,

Antoncic Example 50		
Losartan Potassium	50 mg	69.5%
Microcrystalline cellulose	60 mg	63.3%
Polyethylene glycol in the film coating formulation	0.4 mg	0.9975 % which rounds to 1%
Antoncic Example 52a	Weight, mg	Component weight %/ finished dosage form
Losartan potassium	100 mg	29.74
Silicified Microcrystalline Cellulose	199.2 mg	40.0
Finished dosage weight total (plus 0.22 mg of talc)	336.22	
Antoncic example 52b		
Losartan potassium	100.00 mg	29.74
Silicified Microcrystalline Cellulose	19932 mg	40
Stearic acid	2.1 mg	0.6
Finished dosage weight total (plus 0.22 mg of talc)	336.22	

In Antoncic's example 50 above calculation of % weight of polyethylene glycol with reference to the finished dosage weight as shown in the above table yields 0.9975% which renders the stabilizer weight of 1-10% ,the % weight of the stabilizer claimed in instant claims obvious. Calculation of % weight of microcrystalline cellulose

in the formulations above yields a weight % of 63 in example 50 to 40 in examples 52a and 52b. Antoncic does not specifically teach the exact amounts claimed in instant claims 1,6 and 18. However, it would be within the skill of an ordinary artisan to be able to modify the weight ratio of the excipients in order to obtain the desired stability and bioavailability profile of Losartan. It is also noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Antoncic discloses that Losartan is used as an effective drug for the treatment of hypertension (col.1, lines 26-29, col.3, line 65 to col. 4, line 1) Antoncic additionally discloses that the pharmaceutical composition of his invention can be in a form suitable for peroral or parental application and is e.g. indicated for treating hypertension (col.16, lines 3-5) in addition to teaching the use of crystalline potassium salt of losartan for manufacturing a medicament for the treatment of hypertension (col. 17, lines 40-42). Accordingly, Antoncic renders instant claims 18 and 19 obvious.

In view of the above reference it would have been prima facia obvious to an ordinarily skilled artisan to develop a composition comprising polymorph form of losartan with the instantly claimed excipients at the concentration ranges claimed. Antoncic teaches compositions comprising polymorphic forms of potassium salt of losartan with pharmaceutical excipients which includes silicified microcrystalline cellulose, a stabilizer such as polyethylene glycol, Stearic acid etc. Antoncic additionally teaches that the composition can be used for treating hypertension. As such an ordinarily skilled artisan

would have been motivated to utilize the teachings of Antoncic and develop a composition thus arriving at the instantly claimed composition. An ordinarily skilled artisan would have a reasonable expectation of success that such a composition would offer a more stable formulation for treatment of hypertension.

Response to applicant's arguments filed on 08/14/2009:

In light of the new grounds of rejection above, the arguments submitted on 08/14/2009 which was for the previously submitted rejection is moot.

Conclusion

Claims 1-6 and 18-19 are rejected. Claims 8-10 are objected

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 7.00 am to 4.00 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614